

NDA 18-977/S-024

G.D. Searle & Co.  
Attention: Doranne Frano, Associate Director  
Worldwide Regulatory Affairs  
490 1 Searle Parkway  
Skokie, IL 60077

MAY 14 1998

Dear Ms. Frano:

Please refer to your supplemental new drug application dated July 14, 1998, received July 15, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tri-Norinyl (norethindrone and ethinyl estradiol).

We acknowledge receipt of your submission dated September 21, 1998.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effectuated' under 21 CFR 314.70(c).

This supplemental new drug application provides for a labeling revision to change the packaging configuration for Tri-Norinyl 21 and 28 to linear design.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted July 14, 1998). Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you proposed to use for this product. All proposed materials should be submitted in draft or mock-up form, not final printed. Please submit one copy to this Division and two copies of both promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

If a letter communicating important information about this drug product (i.e., a Dear Health Care Practitioner letter) is issued to physicians and other responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

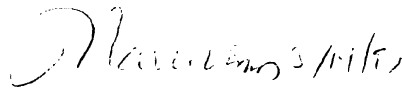
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Please submit one market package of the drug product when available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Jennifer Mercier, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lisa Rarick".

Lisa Rarick, M.D.

Director

Division of Reproductive and Urologic Drug  
Products, HFD-580)

Office of Drug Evaluation III

Center for Drug Evaluation and Research